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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,648	04/13/2000	Zeling Cai	ORT1224	6532

7590 02/17/2004

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/548,648	CAI ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 3, 5, 6 and newly added Claim 7 are pending and being acted upon.

2. Applicant's amendment and remarks, filed 12/17/03 are acknowledged. In view of Applicant's amendments, the previous rejection under the second paragraph of 35 U.S.C. 112 has been withdrawn.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallimore et al. (1998, of record), for the reasons of record as set forth in Paper No. 22, mailed 1/10/03 and maintained in Paper No. 25, mailed 6/25/03.

Applicant arguments, filed 12/17/03, have been fully considered but are not found persuasive. Applicant summarizes the method of the reference and the method of the instant claims and argues that the '777 and '377 patents fail to cure the deficiencies of the reference. It appears that Applicant's argument is based on the addition of new language to Claim 1:

"wherein a source of the MHC class I protein-fluorescent protein fusion molecule is a recombinant cell expressing MHC class I protein fused with a fluorescent protein."

It is the Examiner's position that this new language fails to add any new limitations to the claimed method. First note that whereas the claim is a method claim, the new "limitation" fails to add or actually change any method steps. The claimed method still comprises contacting, incubating, and identifying. Second, it is noted that the new "limitation" actually recites "wherein a source of the MHC class I protein-fluorescent protein fusion molecule". Note the use of "a" instead of "the" - this clearly indicates that the language is not intended to be limiting.

5. The following are new grounds for rejection necessitated by Applicant's amendment and newly submitted IDS.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,284,935 (submitted by Applicant in the IDS on 12/12/03),

The '935 patent teaches a method for the detection of antigen specific T cells (see particularly column 16, lines 22-24 and column 4, lines 37-43) comprising contacting, incubating and identifying T cells with a fusion protein (see particularly column 14, lines 48-50) comprising a MHC Class I (see particularly column 6, lines 28-42), a peptide (see particularly column 3, lines 44-55), and a fluorescent label (see particularly column 14, lines 14-18).

The reference clearly anticipates the claimed invention.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,284,935 (submitted by Applicant in the IDS on 12/12/03).

The method of the '935 patent has been described above. The method differs from the claimed method only in that it does not teach the use of the green fluorescent protein (GFP) label nor the specific use of FACS for identification. As set forth previously, the specification discloses at page 4 last paragraph - page 5 first paragraph, that "it is readily apparent" to those of ordinary skill in the art that a variety of detectable

markers, as well as complexes comprising chemically linked components or indeed "any binding pair partners," might be employed in the claimed method. Also, the specific use of FACS for identification of fluorescent labels was well-known in the art at the time of the invention. Accordingly, the method of the instant claims is obvious in view of the '935 patent.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gallimore et al. (1998, of record) or U.S. Patent No. 5,284,935 (submitted by Applicant in the IDS on 12/12/03), in view of Cai et al. (1996, IDS).

The methods of Gallimore et al. (1998, of record) and the '935 patent have been described. The methods differ from the claimed method only in that they do not employ a recombinant *Drosophila* cell.

Cai et al. teaches the benefits of using a recombinant *Drosophila* cell as a platform for testing APC function. The reference teaches that a recombinant *Drosophila* cell is preferred because non-mammalian cells have reduced costimulatory molecule "background expression" (see particularly page 14736, column 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to a method for the detection of antigen specific T cells comprising contacting, incubating and identifying T cells with a fusion protein comprising a MHC Class I, a peptide, and a fluorescent label, as taught by the '935 patent, employing a recombinant *Drosophila* cell as a platform for the MHC-GFP fusion molecule, as taught by Cai et al. One of ordinary skill in the art at the time the invention was made would have been motivated to employ a recombinant *Drosophila* cell because the method could achieve improved detection given the reduced "background expression" of costimulatory molecules, as taught by Cai et al.

11. No claim is allowed.

12. Applicant's amendment and IDS necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of

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Art Unit: 1644

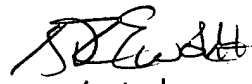
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the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G.R. Ewoldt, Ph.D.
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2/10/04
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